UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: No. 21-mc-1230-JFC MDL No. 3014
PHILIPS RS NORTH AMERICA LLC and PHILIPS NORTH AMERICA LLC, *Plaintiffs*, v. PSN LABS, LLC, *Defendant*.	**COMPLAINT**

Plaintiffs Philips RS North America LLC ("Philips RS") and Philips North America LLC ("Philips NA") (collectively, "Philips" or "Plaintiffs"), by and through their undersigned counsel, bring this action against Defendant PSN Labs, LLC ("PSN"). Plaintiffs' allegations are on knowledge as to themselves and, as to others, on information and belief following a reasonable inquiry.

INTRODUCTION

1. In 2020, Philips RS sought the assistance of third-party labs to research and study the polyester-based polyurethane ("PE-PUR") sound abatement foam used in certain of its sleep and respiratory care devices, as well as its chemical byproducts, including any volatile organic compounds ("VOCs"). Philips RS had received a small number of complaints alleging that the foam was showing signs of degradation, and potential safety concerns had been raised. One of the labs Philips RS turned to, and relied on, was PSN.

2. PSN's Vice President, Dr. Matthew Heidecker, touted PSN's testing services as unmatched in the industry, claiming that PSN could provide Philips RS with "a better quality output at the same (or better) price point" than other labs. PSN also had an additional advantage: it was located in Pennsylvania and was not far from Philips RS's headquarters. Also, PSN had a prior relationship with Philips. In 2019, PSN entered into a contract with Philips NA under which PSN committed to perform any requested and agreed-upon testing and analysis, whether for Philips NA or any of its affiliates, "in a good and workmanlike manner in accordance with all recognized professional standards, ethics and customs," and "with due skill and care, using the proper materials and employing sufficiently qualified staff."

3. As part of an analysis of potential health risks relating to the PE-PUR foam, in 2020 and 2021, Philips submitted orders to PSN for testing and analysis relating to the foam. Dr. Heidecker oversaw PSN's engagement and nearly all aspects of PSN's work. PSN's work—and, even more, its reliability—was critical for Philips RS, because Philips RS was then evaluating the proper corrective action to take with respect to devices containing the PE-PUR foam.

4. In violation of its obligations, PSN committed numerous egregious errors in its testing and associated analysis. For instance, PSN repeatedly insisted that it had identified in the foam a potentially mutagenic and genotoxic VOC called dimethyl diazene that, in reality, is not present in—and is not emitted from—the foam at all. In fact, the "dimethyl diazene" that PSN supposedly detected was actually *acetone*, a naturally occurring and routine compound that does not present anywhere near the potential risks associated with dimethyl diazene. Additionally, PSN insisted it had discovered that certain of the pristine CPAP and Bi-PAP ("PAP") devices it had tested emitted ozone, another potentially toxic chemical. PSN was again incorrect. Ozone is not found in PE-PUR foam, nor is it a byproduct of foam degradation. Eventually, Philips found out

what had happened: PSN had not used an appropriate ozone detector in its testing, and its finding of "ozone" was another error. Then, when preparing its toxicological risk assessment, PSN insisted that another VOC—phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) (hereafter, "phenol")—posed such a risk to PAP users that the devices could not be safely used. Yet, led by Dr. Heidecker, PSN disregarded the safety thresholds for that chemical identified in pre-clinical toxicity studies cited by multiple public health agencies, resulting in PSN vastly overstating the risk presented by the level of phenol it had detected.

5. To be clear, Philips understands that errors—even serious ones, like those committed by PSN here—can happen. But PSN's conduct and behavior extended far beyond mere mistakes. Contrary to what any responsible lab would have done, PSN repeatedly refused to acknowledge even the possibility of its own error, falsely claiming in response to questions regarding its work that Philips as a company did not care about the health of patients. Worse still, when PSN learned of its errors, PSN tried to cover up its own mistakes and doubled down on its incorrect conclusion that the foam was unsafe in order to divert the focus away from its own errors.

6. PSN's cover-up was extensive, and the depths of it have only recently been fully understood by Philips. To cover up its "dimethyl diazene" mistake, PSN refused to provide Philips RS with the raw data from its testing on the grounds that providing the data would somehow "compromise PSN's independence." Philips RS was only able to obtain this raw data years later (long after when Philips RS needed it) by subpoena. PSN ultimately fought providing the raw data to Philips RS for more than two years. Additionally, at the same time that Philips was seeking to independently evaluate PSN's "dimethyl diazene" finding, PSN was manufacturing a biased and skewed analysis to try to vindicate its flawed assessment of the risks posed by dimethyl diazene and phenol. Approximately two weeks after the Philips RS recall began, PSN retained an

"independent toxicologist" to support PSN's interpretation and conclusions. Yet PSN did not provide the independent toxicologist with the raw data necessary to evaluate its purported identification of dimethyl diazene. And, when this independent toxicologist identified profound errors in PSN's assessment of phenol, PSN modified excerpts of a report from the independent toxicologist to omit his conclusion that phenol was *not mutagenic*—a key premise of PSN's risk assessment—when relaying the findings to Philips RS, and later successfully pressured the "independent" toxicologist to change his conclusions as to the appropriate exposure threshold for phenol.

7. After collecting analyses from PSN and others, Philips assembled an independent science panel of esteemed medical researchers and toxicologists to review the full scope of the then-available data. PSN's findings were the only outlier. The scientists on the panel concluded that there was little risk of patient harm from the VOCs PSN had identified. Other independent laboratories, retained by Philips RS to provide data to various health organizations (including the U.S. Food and Drug Administration ("FDA")), reinforced the conclusion that the foam carried a negligible risk of harm after evaluating samples of the same PE-PUR foam PSN had analyzed and performing the same VOC testing on devices containing the foam. In fact, three other laboratories that investigated PE-PUR foam degradation did not identify one of the potentially hazardous VOCs that PSN mistakenly reported (dimethyl diazene) at all, and further testing has shown that the other compounds of concern that PSN identified were well within accepted toxicological threshold levels, often *a hundred (or more) times below* levels of actual potential harm for users.

8. Ultimately, PSN's errors and cover-up caused significant damage to Philips. In June 2021, in reliance on PSN's work, Philips RS initiated a worldwide recall of more than 15

million sleep and respiratory care devices. In July 2021, the FDA classified this recall as a Class I recall, reserved for products that pose a risk of causing serious adverse health consequences or death. Philips RS has spent hundreds of millions of dollars toward this recall and would have pursued a different and more focused recall had PSN not made its serious mistakes and greatly overestimated the potential threat to patients.

9. Through this action, Philips RS and Philips NA seek to recover from PSN for the significant expenses they incurred and reputational harm they suffered in connection with the recall as a result of PSN's wrongs. Philips RS and Philips NA also seek to recover from PSN for the harm they suffered from PSN's efforts to cover up its own mistakes and undermine the conclusion that the foam, in fact, was not toxic. PSN's errors and its cover-up profoundly damaged the longstanding goodwill associated with the Philips brands and marks.

PARTIES

10. Plaintiff Philips RS North America LLC is, and at all relevant times was, a Delaware limited liability company with its principal place of business in Pennsylvania. Philips RS designed and manufactured PAP devices under the names "Respironics" and "Philips Respironics."

11. Plaintiff Philips North America LLC is, and at all relevant times was, a Delaware limited liability company with its principal place of business in Massachusetts. Philips NA sold certain of the devices manufactured by Philips RS.

12. Defendant PSN Labs, LLC is a Pennsylvania limited liability company headquartered in Pennsylvania. It was previously incorporated under the name Advanced Solutions Network, LLC.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because Plaintiffs and Defendant are citizens of different states and the amount in controversy exceeds $75,000.

14. All of the parties are LLCs. Therefore, for purposes of the diversity jurisdiction analysis, the Court looks to the citizenship of the members of the LLCs.

15. Philips RS's sole member is Philips RS North America Holding Corporation, which is incorporated in Delaware and has its principal place of business in Massachusetts. Therefore, Philips RS is a citizen of Delaware and Massachusetts.

16. Philips NA's sole member is Philips Holding USA, Inc., which is incorporated in Delaware and has its principal place of business in Massachusetts. Therefore, Philips NA is also a citizen of Delaware and Massachusetts.

17. PSN's sole member is Michael Alabran, PSN's President, who is a citizen of Pennsylvania. Therefore, PSN is a citizen of Pennsylvania. Accordingly, there is complete diversity of citizenship between the parties.

18. This Court has personal jurisdiction over PSN because it is a Pennsylvania limited liability company headquartered in Pennsylvania. Further, PSN conducted some, if not all, of the testing that is the subject of this Complaint in Pennsylvania. As such, the claims at issue here arise from PSN's conduct and contacts in Pennsylvania.

19. Further, under the Philips General Conditions of Purchase that were incorporated into the agreement between PSN and Philips, PSN and Philips each "consent[ed] to the exclusive jurisdiction of the competent courts in (i) the country or state in which the Philips ordering entity is located; or (ii) at the option of Philips, the jurisdiction of the entity of Supplier to which the order was placed . . . ." Philips RS placed the order for the testing at issue from its

offices in Pennsylvania. Moreover, the purchase order for the testing was sent to PSN's headquarters located in Pennsylvania. As such, the parties agreed to jurisdiction of the courts of the Commonwealth of Pennsylvania.

20. Venue is proper in this District because PSN is headquartered in this District, and the events that give rise to Plaintiffs' claims arise out of PSN's contacts with this District. Further, Philips RS placed the order for the testing at issue through its offices located in this District.

FACTUAL BACKGROUND

21. Philips RS's PAP machines are used to treat certain sleep and respiratory conditions, such as sleep apnea. By delivering a continuous flow of air (or, in the case of Bi-PAPs, air at two different pressure levels) through a mask that is placed over a user's nose and/or mouth, the PAP machine increases air pressure in the user's throat so that the airway does not collapse during inhalation. Thus, use of a PAP device causes the user to inhale air emitted from the PAP device.

22. By 2020, following a limited number of complaints regarding Philips RS's sleep and respiratory care devices, both Philips RS and Philips NA were evaluating the risks associated with PE-PUR foam that had degraded, potentially due to high heat and high humidity conditions. They were also evaluating whether a relatively new and unauthorized cleaning method (ozone) was independently, or in combination with high heat and humidity conditions, causing the foam to degrade. As part of its investigation, Philips RS asked PSN to assess the air emitted from the PAP devices containing sound abatement foam, in order to determine whether a user of such a device might be exposed to hazardous amounts of VOCs in the air flow coming through the device.

I. PSN's Engagement

23. As early as 2018, PSN had expressed interest in assisting Philips with testing. In fact, PSN and Dr. Heidecker lobbied to perform testing for Philips, touting that PSN could provide superior services compared to other labs and would provide Philips with better quality testing at the same (or better) price point.

24. In August 2019, Philips NA entered into a contract (the "Quality Agreement") with PSN. The Quality Agreement set forth "the mutually agreed expectations and obligations" of PSN and permitted "[a]ny . . . Affiliate" of Philips NA, including Philips RS, to "rely on and enforce the provisions of th[e] Agreement." By formally entering into the Quality Agreement, Philips NA was able to add PSN to its list of approved suppliers so that it (or its affiliates) could rely on PSN for potential future testing services. As discussed further below, Philips RS ultimately relied on this Quality Agreement when it later requested that PSN conduct VOC testing on the PE-PUR foam in 2020 and 2021.

25. Section 3 of the Quality Agreement incorporated by reference the "Philips General Conditions of Purchase" in effect at the time. The Quality Agreement also incorporated by reference any subsequent purchase orders between PSN and Philips NA or its affiliates, which would provide the specifications of the particular service or services PSN later agreed to perform.

26. Under the Quality Agreement and the Philips General Conditions of Purchase incorporated therein, PSN agreed to meet certain conditions in the performance of its services. Among other things:

a. ***Standards for PSN's Work.*** PSN agreed that it "shall provide [its] Services in a good and workmanlike manner in accordance with all recognized professional standards, ethics and customs of [PSN's] industry." PSN also agreed to "perform the Services with due skill and care, using the proper materials and employing sufficiently qualified staff."

b. ***Recordkeeping.*** PSN agreed that it "shall have a document control and record retention process in place that complies with the ISO 13485 standard."[1] Section 7.6 of ISO 13485 provides that "[r]ecords of the results and conclusion of validation and necessary actions from the validation shall be maintained" by the lab. In addition, PSN agreed in the General Conditions of Purchase that "any and all [information relating to the work paid for by Philips] . . . shall be kept in good condition. . . ."

c. ***Production of Data and Other Records to Philips Upon Request.*** The General Conditions of Purchase provided that "Philips shall retain all rights in any samples, data, works, materials and intellectual and other property provided by Philips to [PSN]. *All rights in and titles to the Work Product shall become Philips' property*" (emphasis added). "Work Product" was defined as "all deliverables (including future deliverables) and other data, reports, works, inventions, know-how, software, improvements, designs, devices, apparatus, practices, processes, methods, drafts, prototypes, products and other work product or intermediate versions thereof produced or acquired by [PSN], its personnel or its agents for Philips in the performance of Services under the Agreement." Further, the General Conditions of Purchase also provided that "any and all [information relating to the work paid for by Philips] . . . shall be returned promptly upon Philips' first request."

II. PSN's Reckless and Grossly Negligent Conduct

27. Pursuant to purchase orders incorporated by reference in the Quality Agreement, PSN agreed to perform ISO 18562-3 VOC testing on a number of PAP devices, including "VOC [r]un-in and [r]ush VOC [t]esting" for Philips RS. The flawed testing data and

[1] The International Organization for Standardization ("ISO") is an international nongovernmental organization that publishes laboratory testing standards.

risk assessments that PSN would go on to provide proved critical in Philips RS's ongoing efforts to understand (and potentially mitigate) the possible VOC risks posed by devices containing the PE-PUR foam.

A. PSN's Mistaken Detection of Dimethyl Diazene

28. PSN's work would be plagued by material errors. In testing conducted between late 2020 and early 2021, PSN supposedly detected "dimethyl diazene" as a VOC emitted from the PE-PUR foam. Dimethyl diazene is a potentially hazardous chemical, which may be mutagenic and/or carcinogenic, with a presumed threshold of toxicological concern of only 1.5 µg/day.[2] Dimethyl diazene is *not* an expected emission from PE-PUR foam; that is because it is *not* an ingredient in the manufacture of the foam. In fact, no lab other than PSN has ever identified dimethyl diazene as an emission of any PE-PUR foam sample or device containing PE-PUR foam provided by Philips.

29. In reality, PSN had actually detected *acetone*—an organic compound that does not pose anywhere near the same potential hazards to human health as dimethyl diazene. But PSN would provide its mistaken "dimethyl diazene" identification in a number of the reports it issued to Philips RS in the first half of 2021, as discussed further below. And then, after PSN learned that other laboratories had not identified dimethyl diazene as a VOC from *any* of the tested devices, PSN chose not to inform Philips RS that its identification of the compound had been mistaken. Instead, as discussed further below, it opted to silently remove its initial claims of

[2] For unknown compounds that may be deemed mutagenic, FDA initially recommends an initial threshold of toxicological risk of 1.5 µg/day as a standard of "negligible" risk. FDA, M7(R1) ASSESSMENT AND CONTROL OF DNA REACTIVE (MUTAGENIC) IMPURITIES IN PHARMACEUTICALS TO LIMIT POTENTIAL CARCINOGENIC RISK: GUIDANCE FOR INDUSTRY, at 11 (2018), available at https://www.fda.gov/media/85885/download.

dimethyl diazene detection when it provided Philips RS with several revised reports in October 2021—months *after* Philips RS had already begun its recall.

B. PSN's Expedited VOC Testing

30. In March 2021, Philips RS requested that PSN perform VOC testing on a set of Philips RS DreamStation 1[3] devices containing pristine PE-PUR foam. On March 26, 2021, PSN provided the first draft of its results in a report titled "700025-RP-01." This report reflected PSN's VOC testing of a DreamStation 1 device for VOC emissions and included a "toxicological risk assessment" of the VOCs purportedly emitted. PSN would ultimately revise this report seven times between March 26 and July 29, 2021. The report, both in its initial form and through each subsequent revision, was riddled with errors that greatly exaggerated the VOC risks. Unfortunately, Philips RS did not discover those errors until much later on, well after Philips RS had begun its recall.

31. In the first draft of its report, PSN reported that it had detected 0.10 parts per million of "ozone" being emitted from the device.[4] PSN's finding was surprising because neither the device nor its foam component had been cleaned with one of the unauthorized ozone-based cleaning devices then on the market, and ozone is not a chemical ingredient or byproduct of PE-PUR foam. In the first of a long line of instances where PSN would take positions solely to protect PSN, PSN initially claimed it was "unlikely ozone was present or introduced through [its] testing setup." In fact, subsequent investigation determined that PSN's ozone finding was an error

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[3] "DreamStation" is one of the brand names Philips RS used for its PAP devices.

[4] This level exceeds the federal primary standard for ozone in ambient air (.07 parts per million over an 8-hour average) and the amount of ozone that medical devices are permitted to generate (.05 parts per million). *See Ozone National Ambient Air Quality Standards (NAAQS)*, U.S. EPA (Feb. 13, 2024), https://www.epa.gov/ground-level-ozone-pollution/ozone-national-ambient-air-quality-standards-naaqs; 21 C.F.R. § 801.415(c)(1) (2024).

caused by PSN using the wrong ozone detector. PSN had been using an FD-90A-O3-LOW ozone detector to detect ozone gas, which is not recommended for measuring gas emissions from a medical device. No test by any other lab has ever identified ozone emissions from PAP devices that had not been subject to ozone-based cleaning.

32. Next, PSN claimed in the first draft of Report 700025-RP-01 to have identified "dimethyl diazene" emissions from a PAP device. In truth, as discussed above, PSN had not detected dimethyl diazene at all. It had detected acetone. In fact, PSN separately identified acetone as an emission but never checked the possibility that its finding of "dimethyl diazene," which is not a compound expected to be in PE-PUR foam, had been confused with acetone. Even worse, by the fourth revision of its report, PSN doubled down on its error: not only did it conclude that dimethyl diazene was emitted from the devices, but it also concluded that it was emitted in doses far above the tolerable exposure dose.

33. Then, in the fifth revision of its report—*two months* after the first draft of the report—PSN reported, for the first time, that it had detected phenol emissions from the device in excess of a "daily tolerable exposure dose" of 120.0 µg/day. To invoke this exposure threshold number, PSN disregarded specific limits *for phenol* from the available medical literature that are based upon third-party animal studies assessing the toxicological impact of phenol. Instead, PSN incorrectly relied upon default thresholds of toxicological concern, which it obtained from ISO 18562-1, that were *not* specific to phenol. Yet, ISO 18562-1 expressly (a) provides that these *general* thresholds should be used only "if no toxicity data are available" for the *specific* chemicals being assessed, and (b) directs toxicologists to use actual thresholds from accepted toxicological databases or derived from toxicity data for the target compound to arrive at appropriate use

guidelines.[5] To justify the use of ISO 18562-1's general thresholds, PSN claimed that phenol had "no specific pre-clinical toxicological data available in scientific literature, nor a known daily permissible daily [sic] exposure limit." That was incorrect. There were several studies of phenol, reviewed and summarized in Canadian and Japanese government hazard assessment reports, that evaluated phenol-specific thresholds that PSN either missed or chose to disregard.[6]

34. Compounding its error, PSN then lowered its already artificially low "daily tolerable exposure dose" even further, on the grounds that phenol was a "mutagenic" compound. That too was incorrect, as PSN's own outside toxicology consultant would later inform PSN. (*See infra* ¶ 44.) Ultimately, as a result of its errors, PSN wrongly claimed in the fifth revision of its report that the exposure dose threshold for phenol was 1.5 µg/day. Based on that erroneous threshold, PSN claimed that the dosage of phenol emitted by the PE-PUR foam posed a health risk to patients and that, due to its potential classification as a "mutagen," was a "confirmed compound of concern."

35. In truth, using the correct, phenol-specific safety thresholds from the available medical literature, nowhere near a harmful amount of phenol was emitted from PAP devices containing PE-PUR foam, even in worst-case scenarios. Subsequent independent lab

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[5] INT'L ORG. STANDARDIZATION (ISO), BIOCOMPATIBILITY EVALUATION OF BREATHING GAS PATHWAYS IN HEALTHCARE APPLICATIONS (2017).

[6] In 2010, the Canadian department of health ("Health Canada") observed that phenol did not "meet the criteria for high hazard to human health . . . ." HEALTH CAN., SCREENING ASSESSMENT FOR THE CHALLENGE: PHENOL, 2,6-BIS(1,1-DIMETHYLETHYL-4-(1-METHYLPROPYL) (2010), at 1. Moreover, in 2009 and 2011, the Japanese Ministry of Labor and Welfare sponsored pre-clinical toxicology studies of the effect of phenol in rats, concluding that phenol was not genotoxic and *finding a "No Observed Adverse Effect Level" of 12,000 micrograms per kilogram per day* (µg/kg/day). *See* Yoshiyuki Shigeta et al., *Summary Information of Human Health Hazard Assessment of Existing Chemical Substances (VI)*, 138 BULL. OF NAT'L INST. HEALTH SCI. 33-39 (2020).

testing has shown that, even considering the *maximum* detected levels of phenol emitted from the PE-PUR foam, the resulting concentration of phenol would be *dozens of times below* the "No Observed Adverse Effect Level"—*i.e.*, the dosage level where no health impact is expected.

C. PSN's Run-In Report

36. By April 2021, the PE-PUR foam degradation issue had been escalated to senior leadership at Philips' foreign parent company, Koninklijke Philips N.V. ("KPNV"). The company needed reliable risk assessments to determine what mitigation measures would be necessary to protect patients from any adverse effects of PE-PUR foam degradation. Initial findings suggested that foam degradation (without ozone-based cleaning methods) occurred slowly, and complaints of degradation were often concentrated in areas with climates characterized by high temperatures and high humidity. Thus, Philips RS sought VOC testing to assess the potential mitigation measures that may be needed and to complete a holistic risk assessment, to determine whether VOC emissions posed meaningful health risks to users of devices that had *not* experienced foam degradation or been exposed to ozone gas. Absent meaningful VOC risk, the recall and its execution could have been specific to the foam degradation issues and focused on addressing those risks specifically, not the VOC risks that did not exist.

37. In April 2021, while Report 700025-RP-01 was going through multiple revisions, PSN performed analyses of VOC emissions on two new DreamStation 1 PAP devices that had previously been run for 24 hours before testing commenced (commonly referred to as a "run-in" process). PSN documented its findings from this testing in two "Run-In Reports," each addressing a different CPAP device. PSN's run-in testing was significant for evaluating VOC emissions. VOCs diminish over time through use; thus, the "run-in" test helps to identify whether any problematic VOC emissions dissipate within the first 24 hours of use. If so, then conducting a run-in before shipment of a device may mitigate any potential VOC risk to the user.

38. Here, too, in its Run-In Reports, PSN mistakenly found dimethyl diazene as a potential VOC. And again, not only did it find dimethyl diazene, but it found it in potentially hazardous concentrations. As a result, PSN's mistakes in its Run-In Reports significantly impacted decision-making within Philips RS, Philips NA, and KPNV, as according to PSN, the supposed "dimethyl diazene" was still being found after the "run-in" of the product, not just immediately after the device was first turned on.

III. The Recall

39. During this period, Philips RS was considering various corrective action scenarios based on the then-current assessment of the foam degradation risk, including the possibility of using filters as an interim solution to prevent degraded foam from potentially reaching users and potentially executing a recall targeted to older PAP products that were more prone to age-related degradation. But when PSN falsely claimed that PAP devices emitted excessive quantities of gaseous VOCs in devices with non-degraded foam that could not be stopped by a filter, senior leadership of Philips RS was left with little choice other than to consider different and broader actions to eliminate the imagined threat to patients from toxic VOCs.

40. Additionally, in late April and early May 2021, Philips RS was considering a proposal to circulate a Field Safety Notice to patients that would advise strictly limiting use of PAP devices to eight hours a night, so as to reduce the amount of potential exposure to VOCs, a position supported by the then-current draft of PSN's report from April 19, 2021. But by late May, PSN concluded in its revised draft report that dimethyl diazene and phenol emissions would pose a potential health hazard to patients from even eight hours of daily exposure. This, again, was incorrect, as Philips RS learned only later. At the time, however, based on PSN's mistaken concerns, the potential health hazards seemingly could not be avoided with an eight-hour limitation on use time.

41. Thus, when Philips RS finalized its risk assessment, it relied on PSN's (incorrect) conclusions and determined that more drastic action would need to be taken to protect patients. Had PSN corrected its mistaken findings about harmful levels of toxic VOCs (or had PSN never made the mistakes leading to those erroneous findings in the first place), Philips RS would have pursued a different and more focused recall. But because of PSN's erroneous findings, Philips RS was driven to take a much more conservative corrective action.

42. On June 14, 2021, Philips RS voluntarily initiated a massive global recall program due to concerns over the degradation issues with the PE-PUR foam and the VOCs that Philips RS believed, based on PSN's reporting, could be emitted. The FDA classified this recall program as a Class 1 recall, the most serious type of recall reserved for products that may cause serious adverse health consequences or death.

IV. PSN's Post-Recall Misconduct

43. Following the recall, Philips RS performed further research to evaluate and understand the findings of Report 700025-RP-01, to verify the report's accuracy and develop information to more fully articulate potential VOC concerns to patients and medical advisors. This research revealed several of PSN's prior errors, including the misidentification of acetone as dimethyl diazene and PSN's failure to rely upon the compound-specific data for phenol identified in prior studies. As Philips re-evaluated PSN's data and findings, PSN worked to thwart any efforts to cast doubt on its faulty science and tried to undermine the research and findings of other Philips NA and Philips RS employees, as well as the conclusions of independent toxicologists. Rather than fessing up and admitting it made mistakes, PSN doubled down on those mistakes in an attempt to preserve its reputation and justify its erroneous findings.

A. PSN's Outside Toxicology Consultant

44. By late June 2021, without obtaining authorization from Philips, PSN contacted an outside toxicology consultant to perform a re-analysis of PSN's risk assessment provided in Report 700025-RP-01. Dr. Heidecker received reports from the third-party consultant following the consultant's initial review of PSN's report. The reports correctly noted that phenol was *neither mutagenic nor genotoxic*. This finding contradicted PSN's previous assessment (¶¶ 33-35, *supra*), which classified phenol as mutagenic and thus applied a far more restrictive safety threshold than it should have in its testing report. For comparison, PSN had initially provided a daily tolerable exposure dose for phenol of only 1.5 µg per day, based on its conclusion that the compound was mutagenic. The third-party toxicology consultant, on the other hand, concluded that phenol was, in fact, not mutagenic and therefore had determined a safe level of 351,120 µg per day: *over 200,000 times greater* than the flawed threshold PSN had applied in its analysis.

45. Faced with these findings showing that PSN's guidance to Philips—which Dr. Heidecker had confidently asserted was "not only accurate but forward looking"—was off by a factor of hundreds of thousands, PSN pressured its so-called independent consultant to change his numbers. Instead of having the consultant consider medical literature on the actual thresholds for phenol, such as the studies reported by the Japanese and Canadian governments (¶ 33, *supra*), PSN coaxed the consultant into looking at other surrogates for phenol in order to lower his daily tolerable exposure level. Using one of these different surrogates, the toxicology consultant calculated a new daily tolerable exposure level of 140 µg per day—still nearly ***100 times greater*** than what PSN had applied in the most up-to-date draft of Report 700025-RP-01. Tellingly, with a daily tolerable exposure level of 140 µg per day, the highest possible dose of phenol predicted in PSN's assessment (12.7 µg per day) would have been well below the daily tolerable exposure.

Thus, even after PSN pressured its independent expert into making these revisions, the revised report *still* demonstrated that PSN was incorrect in concluding that phenol presented a safety risk to patients. Yet, PSN never revised Report 700025-RP-01 to reflect the alternative, substantially higher toxicology thresholds proposed by its third-party toxicologist.

B. Undermining Findings on Phenol

46. PSN also attempted to hide the truth concerning its false conclusions about phenol by channeling biased information to Philips. Following the voluntary recall notification, Philips RS asked another third-party consultant to review Philips' internal assessment of the VOCs. On July 17, 2021, this third-party consultant provided Philips with his hazard profile assessment for phenol, concluding (much like the consultant PSN contacted) that "the preponderance of the evidence indicates that [phenol] is not mutagenic." This assessment was based in part on a screening assessment conducted by Health Canada (the "Health Canada Report"), the Canadian government's department responsible for national health policy.

47. The July 2021 hazard profile assessment performed by Philips' third-party consultant directly contradicted PSN's earlier May 24, 2021 draft testing lab report, which mistakenly classified phenol as a potential mutagen with "no specific pre-clinical toxicological data available in scientific literature, nor a known daily permissible daily [sic] exposure limit."

48. In its attempt to preserve its reputation and justify the need for the massive recall that Philips RS had already undertaken, PSN sought to undermine the toxicological risk assessment provided by Philips' third-party consultant. In October 2021, PSN's Dr. Heidecker circulated an article (the "Advocacy Article") written by two advocacy groups that disagreed with the Health Canada Report and that claimed that phenol is an "inherently toxic chemical." The Advocacy Article was prepared by Chemical Sensitivities Manitoba ("CSM"), a volunteer non-governmental organization dedicated to raising awareness of supposedly toxic chemicals in the

home and the environment, and the Canadian Environmental Law Association ("CELA"), a non-profit organization that advocates for environmental law reform. Whereas the Health Canada Report cites specific studies demonstrating the health effects of exposure to phenol, the Advocacy Article from CSM and CELA does not cite a single study to support its "inherent toxicity" conclusion and made no effort to contradict the Health Canada Report's analysis.

49. Dr. Heidecker ignored the obvious bias of CSM and CELA and feigned as if the Advocacy Article somehow superseded the Health Canada Report, despite the lack of any empirical support for the Advocacy Article's claim that phenol is "inherently toxic." Dr. Heidecker specifically coordinated PSN's timing and messaging that would be used to disseminate the Advocacy Article within Philips, so as to maximize possible disruption to Philips' investigation.

C. Concealing Prior Mistakes

50. Beginning in August 2021, for purposes of completing its records, Philips RS asked PSN to finalize the two Run-In Reports that PSN originally provided in April 2021. PSN only provided revised reports on October 6, 2021 and—only then—in a misleading fashion designed to hide its prior mistakes. The two revised reports made significant changes to the findings from the original reports and did so in an effort to obscure PSN's prior mistakes. Critically, the October 2021 versions of these reports *omitted* any claims that PSN had detected dimethyl diazene, not once explaining why this prior mistaken finding had been dropped. PSN gave Philips RS no notice that it had made this dramatic revision and offered no explanation as to why its findings had so drastically changed.

V. PSN's Refusal to Return Philips Property

51. PSN disrupted Philips' ability to provide timely, complete, and accurate information to patients and regulators by defying the terms of its contract and refusing to turn over raw data and other underlying information related to PSN's flawed testing.

52. In an effort to understand PSN's findings of dimethyl diazene, on July 26, 2021, Philips RS requested that PSN provide for Philips' review the raw data from the experiments that resulted in the 700025-RP-01 report. After numerous follow-up emails, PSN refused to produce the raw data that Philips was contractually entitled to receive, claiming PSN had produced all "pertinent" data. After months of requests, all the way through October 2021, Philips RS again requested (through counsel) the full set of raw data. In response, PSN's President, Michael Alabran, protested that it is "not standard practice . . . to share most forms of raw data as that can compromise our impartiality position . . . ." When pressed to provide the data, PSN claimed—baselessly—that Philips "falsified a document in an attempt to obtain the requested data" and again refused to provide any of the raw data. Then, in November 2021, Alabran told Philips that "PSN reports of regulatory record . . . will not, under any circumstance, make available data that could compromise PSN's independence." For months, PSN argued with Philips over the return of Philips' work product. Only through a legal subpoena—years into litigation that had been filed against Philips relating to the recall—was this raw data eventually produced by PSN.

53. Additionally, on February 14, 2022, Philips provided a list of questions to PSN regarding some of its prior findings. In particular, Philips asked PSN to provide the mass spectroscopy data it used to specifically identify dimethyl diazene in the 700025-RP-01 report and the methods by which dimethyl diazene had been detected. Philips also asked why the VOC profiles identified in PSN's ozone report followed irregular trends and how dimethyl diazene had

been detected in that reporting. PSN answered these questions on February 24, 2022 and provided at least a portion of its mass spectroscopy data.

54. But from later communications with PSN's counsel, Philips now understands that—in defiance of PSN's contract with Philips and good laboratory practice—PSN actually destroyed the majority of internal communications within PSN related to the work performed for Philips. To date, Philips' counsel has been unable to obtain a clear explanation from PSN's counsel about PSN's data retention policy and whether it complied with the terms of PSN's engagement with Philips.

CLAIMS FOR RELIEF

COUNT I – CONTRACTUAL INDEMNIFICATION

55. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

56. Philips' General Conditions of Purchase provide that "*Supplier [i.e., PSN] shall indemnify and hold harmless Philips [and] its Affiliates . . . from and against all suits*, actions, legal or administrative proceedings, claims, demands, damages, judgments, liabilities, interest, *attorneys' fees, costs and expenses of whatsoever kind or nature* (including but not limited to special, indirect, incidental, consequential damages), whether arising before or after completion of the delivery of the Goods or performance of the Services covered by the Agreement, *in any manner caused or claimed to be caused by the acts, omissions, faults, breach of express or implied warranty, breach of any of the provisions of this Agreement, or negligence of Supplier*, or of anyone acting under its direction or control or on its behalf, in connection with Goods, Services or any other information furnished by Supplier to Philips under the Agreement" (emphasis added).

57. PSN provided Philips RS and Philips NA with inaccurate testing reports that significantly impacted the recall, its execution and its associated costs. Philips RS and Philips

NA also spent millions to cover settlements and in attorneys' fees, costs, and expenses related to the ensuing litigation.

58. PSN is contractually obligated to indemnify Philips RS and Philips NA for the various recall-related costs, as well as Philips RS's and Philips NA's attorneys' fees, costs, and expenses, necessitated by PSN's false conclusions regarding toxic VOCs emitted from the PE-PUR foam.

59. Accordingly, Philips RS and Philips NA have been harmed and seek indemnification in an amount to be proven at the trial of this matter.

COUNT II – BREACH OF CONTRACT
(Failure to Provide Contractually Adequate Testing Services)

60. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

61. The 2019 Quality Agreement for Service Suppliers – Test & Measurement (the "Quality Agreement") constitutes a valid and binding contract between Philips NA, Philips RS (as an affiliate under the Quality Agreement), and PSN.

62. Under Section 3 of the Quality Agreement, the "Agreement applies to Services provided by [PSN] on request of [Philips NA] or any Affiliate of [Philips NA]. Any such Affiliate may rely on and enforce the provisions of th[e] Agreement[.]" Philips RS can therefore enforce the terms of the Quality Agreement.

63. Section 6 of the Quality Agreement expressly provides that "[PSN] shall provide the Services in a good and workmanlike manner in accordance with all recognized professional standards, ethics and customs of [PSN's] industry." The Philips General Conditions of Purchase also states that "[PSN] shall perform the Services with due skill and care, using the proper materials and employing sufficiently qualified staff."

64. The "recognized professional standards" that PSN was obligated to comply with are those provided by the International Organization for Standardization ("ISO").

65. Under ISO/IEC 17025[7] Section 4.1.1, all "[l]aboratory activities *shall be undertaken impartially* and structured and managed as to safeguard impartiality" (emphasis added). Further, ISO/IEC 17025 Section 6.4.1 provides that PSN was required to have "access to *equipment . . . that is required for the correct performance of laboratory activities*" (emphasis added). Additionally, ISO/IEC 17025 7.2.1.1 required PSN to "use *appropriate methods and procedures* for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data" (emphasis added).

66. PSN violated each of these standards. PSN did not perform its analysis with due care, including through the misidentification of acetone as dimethyl diazene. PSN further failed to fully evaluate the available scientific literature of the toxicity of phenol and did not present information about phenol in an even-minded, unbiased and credible fashion. PSN also violated the applicable standards by using an incorrect ozone detector that was incapable of reliably measuring ozone concentrations in the range necessary to ensure compliance with FDA regulations. PSN's activities, far from being performed impartially, were also performed with a plain bias against Philips. PSN therefore breached its obligations under the Quality Agreement.

67. Philips RS and Philips NA have performed all of their obligations and have not violated any of their obligations under the Quality Agreement.

[7] This ISO standard was developed with the International Electrotechnical Commission ("IEC").

68. PSN's various mistakes caused the vast overestimation of the potential VOC risks posed by the PE-PUR foam. Philips RS and Philips NA relied on PSN's flawed testing reports and risk assessment in their decision-making regarding the recall and its execution.

69. As a result of PSN supplying a flawed risk assessment and its impact on the recall, Philips RS's and Philips NA's reputations were harmed and both suffered significant pecuniary losses in connection with the recall. Accordingly, Philips RS and Philips NA are entitled to an award of damages in an amount to be determined at trial.

COUNT III – BREACH OF CONTRACT
(Failure to Adequately Maintain Records)

70. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

71. PSN violated the Quality Agreement when it failed to adequately maintain records of the work it performed for Philips, as required under the General Conditions of Purchase.

72. Section 12.1 of the General Conditions of Purchase provides that "[a]ll machinery, tools, drawings, specifications, raw materials and any other property or materials furnished to Supplier by or for Philips, or paid for by Philips, for use in the performance of the Agreement, shall be and remain the sole exclusive property of Philips and shall not be furnished to any third party without Philips' prior written consent, and all information with respect thereto shall be confidential and proprietary information of Philips. In addition, any and all of the foregoing shall be used solely for the purpose of fulfilling orders from Philips, shall be marked as owned by Philips, shall be held at Supplier's risk, shall be kept in good condition and, if necessary, shall be replaced by Supplier at Supplier's expense, shall be subject to periodic inventory check by Supplier as reasonably requested from time to time by Philips, and shall be returned promptly upon Philips' first request. Except as otherwise expressly agreed in writing, Supplier agrees to

furnish at its own expense all machinery, tools, and raw materials necessary to perform its obligations under the Agreement."

73. Further, Section 5.3 of the Quality Agreement states that PSN "shall have a document control and record retention process in place that complies with the ISO 13485 standard (as applicable)[.]" Under ISO 13485, "[t]he quality management system documentation . . . shall include: . . . documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes." Such "[r]ecords shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system." Moreover "[t]he organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. . . . The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization."

74. PSN was therefore required by the contract's terms—as well as under ISO 13485, as referred to therein—to maintain records of the work it performed for Philips, including internal communications relating to its work.

75. PSN breached this contractual obligation when it apparently destroyed most of the lab's internal communications related to its work for Philips RS and Philips NA. As a result, Philips RS and Philips NA suffered damage to their property.

76. Further, Philips RS and Philips NA suffered pecuniary losses when they expended significant resources, including through issuing a subpoena to PSN and negotiating the production of documents in response to that subpoena, to obtain the testing records to which they were contractually entitled.

77. Accordingly, Philips RS and Philips NA are entitled to an award of damages in an amount to be determined at trial.

COUNT IV – BREACH OF CONTRACT
(Failure to Return Philips Property)

78. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

79. PSN breached the Quality Agreement by failing to provide the testing data that Philips RS requested, as required under the Quality Agreement and the General Conditions of Purchase.

80. Under the General Conditions of Purchase incorporated in the Quality Agreement, Philips NA and its affiliates, including Philips RS, "shall retain all rights in any samples, data, works, materials and intellectual and other property provided by Philips to Supplier. All rights in and titles to the Work Product shall become Philips' property . . . ." The General Conditions of Purchase define "Work Product" as "all deliverables (including future deliverables) and other data, reports, works, inventions, know-how, software, improvements, designs, devices, apparatus, practices, processes, methods, drafts, prototypes, products and other work product or intermediate versions thereof produced or acquired by Supplier, its personnel or its agents for Philips in the performance of Services under the Agreement." As such, under the terms of PSN's agreement, the raw data underlying PSN's VOC testing performed for Philips was "Work Product" and became Philips's property.

81. Pursuant to these provisions, Philips NA and Philips RS have a proprietary interest in all testing data created by PSN at Philips' request, and PSN was required to provide such testing data to Philips NA and Philips RS upon request. However, when Philips RS and its

counsel requested such testing data from PSN on multiple occasions in 2021, PSN delayed, lied, and ultimately refused to provide the requested data, thereby breaching the terms of the contract.

82. As a result of not being provided with all the data upon request, Plaintiffs suffered pecuniary damages by having to expend significant resources, including through issuing a subpoena to PSN and negotiating the production of records in response to that subpoena, in order to acquire the data that Philips NA and Philips RS were contractually entitled to receive.

83. Philips NA and Philips RS are therefore entitled to an award of damages in an amount to be determined at trial.

COUNT V – BREACH OF IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

84. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

85. Throughout its work for Philips NA and Philips RS, PSN engaged in various misconduct that ultimately undermined its obligation to provide Philips NA and Philips RS with reliable testing data and an accurate risk assessment of the potential harm to patients posed by PE-PUR foam. By spreading misleading information and doubling-down on its errors, PSN sought to influence Philips' internal deliberations and push Philips toward accepting PSN's flawed conclusions.

86. Further, without any authorization from Philips NA or Philips RS, PSN requested an outside toxicology consultant to perform an analysis of PSN's flawed risk assessment. PSN's Vice President (Dr. Matthew Heidecker) subsequently pressured this toxicology consultant to criticize the approach taken by the other independent consultants that Philips had retained and encouraged this consultant to adopt PSN's mistaken conclusions in order to preserve PSN's reputation. To the extent that the retention of this independent toxicologist was informed by a

need to obtain a better informed understanding of phenol, PSN breached the implied covenant of good faith and fair dealing by ensuring that the conclusions were misreported.

87. Consequently, as a result of PSN repeatedly undercutting one of the purposes of its engagement with Philips—that is, to provide competent and independent analysis of any risks posed to users by PE-PUR foam—PSN violated its duty of good faith and fair dealing that is implied in all contracts.

88. PSN's biased and inaccurate testing results and its associated misconduct improperly led Philips RS and Philips NA to greatly overestimate the potential VOC risks posed to patients by PE-PUR foam. Philips RS and Philips NA relied on PSN's flawed assessment in their decision-making regarding the recall and its execution. Philips RS's and Philips NA's reputations were harmed, and both suffered significant pecuniary losses.

89. Accordingly, Plaintiffs are entitled to an award of damages in an amount to be determined at trial.

COUNT VI – NEGLIGENCE

90. Plaintiffs repeat and re-allege the foregoing paragraphs of this Complaint as though fully set forth in this paragraph.

91. PSN's many mistakes throughout the course of its work for Philips not only violated the Quality Agreement, as well as the professional standards incorporated in the Quality Agreement, but also constituted professional negligence.

92. PSN departed from accepted industry standards by, among other things, performing a toxicological risk assessment without the necessary expertise in toxicology, providing biased work that was undermined by a clear prejudice against Philips, and using improper procedures, methodology, and equipment in preparing its testing reports.

93. PSN's negligence directly and proximately damaged Philips RS and Philips NA, and they are entitled to an award of damages, including punitive and/or exemplary damages, in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask for the following relief:

1. Judgment in favor of Plaintiffs and against Defendant, for damages in such amounts as may be proven at trial;

2. Punitive and/or exemplary damages in such amounts as may be proven at trial;

3. Attorneys' fees, costs, and expenses pursuant to the Quality Agreement and the Philips' General Conditions of Purchase incorporated therein;

4. Pre- and post-judgment interest; and

5. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: July 29, 2024

Respectfully submitted,

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* Plaintiffs' counsel has already been admitted *pro hac vice* in this litigation, and the requirements of Local Rules 83.2(A)(3) and 83.2(B) have been waived. *See* ECF No. 4, ¶ 6.